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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,498	07/18/2002	Wolf-Georg Forssmann	P67748USO	2430

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EXAMINER
AUDET, MAURY A

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,498	FORSSMANN ET AL	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *04/08/2002* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it unclear whether the use of urodilatin is capable of BOTH improving residual renal function in patients with chronic renal insufficiency before obligatory dialysis and for prolonging the dialysis-free intervals in patients with chronic renal insufficiency, or only one or the other based on the use of "and/or". It is suggested that Applicant amend the claims to be

drawn to 1 or the other method of use, or to both, assuming applicant may point out where adequate support may be found for both in the specification.

Claims 1-2 (as to being drawn to improper "Use" claims under U.S. patent law) provides for the use of urodilatin for improving residual renal function in patients with chronic renal insufficiency before obligatory dialysis and/or for prolonging the dialysis-free intervals in patients with chronic renal insufficiency (claim 1) and clearance of fluid and urinary waste substances into the abdominal cavity in patients with chronic renal insufficiency by adding urodilatin to the peritoneal dialysate of such patients (claim 2), but, since the claim *does not set forth any steps* involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Although it is unclear whether the claims are drawn to compounds or methods of use (since there are no steps, other than implied administering of urodilatin), the claims have been examined as being drawn to methods of use, based on an implied administering step.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 8806596 (BISSENDORF PEPTIDE GMBH).

As discussed above, the invention is drawn to the use of urodilatin for improving residual renal function in patients with chronic renal insufficiency before obligatory dialysis and/or for prolonging the dialysis-free intervals in patients with chronic renal insufficiency (claim 1) and clearance of fluid and urinary waste substances into the abdominal cavity in patients with chronic renal insufficiency by adding urodilatin to the peritoneal dialysate of such patients (claim 2).

WO 8806596 teach the use of urodilatin for renal disorders [i.e. chronic], including such renal disorder species pre-terminal renal insufficiency [i.e. chronic renal insufficiency] (claims 12-13, and page 13, ¶ 1), as well as for diuretic use by rapid increase in diuresis and sodium excretion [i.e. clearance of fluid and urinary waste for dialysis, such as peritoneal dialysis] (claims 29 and 37; page 4, ¶2 and page 16, ¶2).

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (US 5565428).

Clark et al. teach the use of urodilatin in treating chronic renal insufficiency, involving peritoneal dialysis (column 12, lines 12-19; column 6, lines 11-18; column 2, lines 34).

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (US Eur J Med Res. 1998 Feb 21;3(1-2):103-110. Review.).

Meyer et al. teach the use of urodilatin, as an agent which "induces diuresis and natriuresis . . . [to] physiologically regulate[] fluid balance and sodium homeostasis" (page 103,

¶2, lines 7-10), in "reduction in hemodialysis/hemofiltration [HD/HF]" . . . for the prophylactic use of URO [i.e. chronic renal insufficiency] (page 103, ¶ 4). Meyer et al. discusses that 5/6 studies of urodilatin in acute renal failure (ARF) significantly reduced frequency of HD and duration of HF compared to the placebo-treated patients (page 106). In the one study that was not conclusive, it was indicated that 75 patients died and that the lack of prophylaxis by urodilatin may have been due to the "the multi-morbidity and the serious clinical conditions" of the patients in that study [i.e. end-stage renal failure] and that therapy was started too late in the disease process (page 106-107). Meyer et al. go on to teach that in such in renal therapy "a prophylactic approach in the use of URO [urodilatin] might be more promising" [i.e. chronic renal insufficiency, prior to acute renal insufficiency or ARF] (page 107, ¶ 1). Meyer et al. summarized that "there are clinical studies . . . significantly reducing the incidence of HD/HF, using URO" (page 107, ¶ 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 8806596 (BISSENDORF PEPTIDE GMBH), Clark et al. (US 5565428), and Meyer et al. (US Eur J Med Res. 1998 Feb 21;3(1-2):103-110. Review.) in view of Fluge et al. (US 5571789).

WO 8806596, Clark et al., and Meyer et al. are all discussed above.

Fluge et al. teach that :

> Moreover, intravenous application of urodilatin will increase the glomerular filtration rate, the excretion of water, sodium and chloride without the hypotensive effect observed with a similar dosage of ANP. Thus, especially with subjects having a labile circulation urodilatin provides less side effects. The relaxation of the vascular smooth muscles will result in a hypotensive effect only with higher urodilatin doses.

If not apparent in the references themselves, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use urodilatin for improved renal function in chronic renal insufficiency either pre-dialysis or in peritoneal (abdominal) dialysis in the methods of any of WO 8806596, Clark et al., and Meyer et al. in view of Fluge et al., because Fluge et al. expressly teach the advantageous use of urodilatin as capable of increasing the glomerular filtration rate of the kidneys, whether through the urinary tract system or into an alternative filtration space such as the abdomen/peritoneal cavity, and because each of the primary references teach the use of urodilatin to improve renal function in renal disorders such as chronic renal insufficiency.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
December 13, 2003

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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